510k Summary

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Contact:

Howard Schrayer
Orthocon, Inc.
1 Bridge Street, Suite 121
Irvington, NY 10533
Telephone: 914-357-2600
Fax: 914.231.7884
hs.ss@verizon.net

NOV 2 1 2012

Date Prepared: October 21, 2012

Device Trade Name: Hemasorb® Resorbable Hemostatic Bone Putty Applicator

Manufacturer:

Orthocon, Inc.
1 Bridge Street, Suite 121
Irvington, NY 10533

Common Name: Bone wax

Classification Name: Bone wax (unclassified)

Class: Unclassified

Product Code: MTJ

Indications for Use:

Hemasorb Resorbable Hemostatic Bone Putty is indicated for use in the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade. The material may be used during surgical procedures and in treating traumatic injuries. Hemasorb Resorbable Hemostatic Bone Putty is also indicated for use in the control of bleeding from bone surfaces in cardiothoracic surgery following sternotomy.

Device Description:

The Hemasorb Resorbable Hemostatic Bone Putty Applicator (Hemasorb® *apply*) is a syringe-type applicator containing Hemasorb Resorbable Hemostatic Bone Putty. Use of the applicator will allow convenient discharge of the putty into the surgeon's hand, onto a surgical instrument, or directly onto bleeding bone. The tip of the applicator is beveled and made from a softer material than the applicator barrel to assist with spreading the material onto the bone.

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Hemasorb Resorbable Hemostatic Bone Putty is a sterile, soft, moldable, biocompatible, absorbable material of putty-like consistency intended for use in the management of bleeding from bone surfaces by acting as a mechanical barrier or tamponade. The putty is a mixture of calcium stearate, Vitamin E acetate, and a liquid surfactant. When applied manually to surgically incised or traumatically broken bone, Hemasorb Resorbable Hemostatic Bone Putty achieves local control of bleeding by acting as a mechanical barrier (tamponade).

Substantial Equivalence and Predicate Devices:

The Hemasorb Resorbable Hemostatic Bone Putty Applicator was shown to be substantially equivalent to the devices cleared under K102762, K111575, and K113627 with respect to intended use, technological characteristics and performance.

Performance Testing:

In vitro testing demonstrated that the performance of the Hemasorb Resorbable Hemostatic Bone Putty Applicator was substantially equivalent to that of the predicate devices. The biocompatibility and extractable tests that demonstrate that the materials are safe and substantially equivalent to the predicate device are:

- Cytotoxicity
- Irritation (Intracutaneous Injection)
- Acute Systemic Injection
- HPLC Analysis of putty in contact with the dyed plunger
- Evaluation of Ignition Potential

Conclusion:

The Hemasorb Resorbable Hemostatic Bone Putty Applicator (Hemasorb *apply*) is substantially equivalent to the predicate device with respect to intended use, technological characteristics and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Orthocon, Incorporated
% Richard Kronenthal, Ph.D.
Chief Scientific Officer
1 Bridge Street, Suite 121
Irvington, New York 10533

Letter Dated: November 21, 2012

Re: K121953
Trade/Device Name: Hemasorb Apply
Regulatory Class: Unclassified
Product Code: MTJ
Dated: October 21, 2012
Received: October 23, 2012

Dear Dr. Kronenthal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K121953

Device Name: Hemasorb Applicator

Hemasorb Resorbable Hemostatic Bone Putty Applicator is indicated for use in the control of bleeding from cut or damaged bone by acting as a mechanical barrier or tamponade. The material may be used during surgical procedures and in treating traumatic injuries. Hemasorb Resorbable Hemostatic Bone Putty is also indicated for use in the control of bleeding from bone surfaces in cardiothoracic surgery following sternotomy.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K121953